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Innovamed Health, LLC

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San Antonio, TX 78258
Telephone: 877-475-7050

Section 5: 510(k) Summary

Date Prepared: October 22, 2013

510(k) Number: K 133274

Sponsor

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Contact Person

Joe Adkins, Senior Project Manager
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Device Name

Trade Name: "Vena Pro" Vascular Therapy System
Model Number: VP-3111
Common or Usual Name: Compressible Limb Sleeve Device
Classification Name: Compressible Limb Sleeve Device
Class II
Product Code: JOW
Regulation Number: 21 CFR 870.5800

Identification of Predicate Devices

Wildcat Medical Equipment, Inc., TriplePlay TPVT-01	K103187
Doctor's Orders, Inc., DVTCare CA5	K061125
Medical Compression Systems, LTD, WizAir DVT	K023573
Dynamic Air, Inc., TravelAir Portable Compression System	K022340
Microtek Medical, Inc., Venodyne DVT Advantage Plus	K011318

Device Description

The Vena Pro Vascular Therapy System is a lightweight, portable, rechargeable battery powered **prescriptive device** that is intended to be used in the home or clinical setting by or under the direction of a medical professional to help stimulate blood flow as an aid in the prevention of deep vein thrombosis (DVT).

The system utilizes pneumatically controlled, single chamber cuffs actuated by an electronically controlled air pump unit and solenoid valve. All pump, battery and control components are protectively housed in a plastic case that is permanently attached to a single use inflatable cuff. A single tactile touch control switch, tri-color LED for ON, LOW BATTERY, CHARGING and CHARGE COMPLETED indication, and a blue LED (for indicating a leak or low pressure alarm) provides for user interface. There is also a port for connecting the battery charger/AC adapter plug, and a currently unused port for future use in usage data reporting.

The leg wrap (cuff) component consists of a Polyvinyl Chloride (PVC) air bladder encased inside a soft, non-woven medical fabric made from Dupont Softesse (a Polyester blended medical fabric) or equal , which is adhered to the PVC air bladder. The units are supplied clean, non-sterile, packaged in pairs (1 left and 1 right side).

In operation, the user simply turns the power ON via the single button I/O control switch. A single user "cuff" containing air bladders is permanently connected to the unit. The control unit then fills the cuff to a pre-determined pressure (50 mmHg). Cuff pressure is monitored by an internal pressure switch and system software. Once the pressure reaches the proper level, the pump is turned OFF for an approximately 50 second "rest" period, and the cuff deflates to ambient pressure through a valve inside the plastic case. After the "rest" period, the cycle repeats until the unit is turned off.

Intended Use

The Vena Pro Vascular Therapy System model VP-3111 is intended to be an easy to use portable system, prescribed by a physician, to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device can be used in the home or clinical setting to:

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs;
- As a prophylaxis for DVT by persons expecting to be stationary for long periods of time.

Contraindications

The Vena Pro Vascular Therapy System model VP-3111 ***must not*** be used to treat the following conditions:

- Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, congestive heart failure, thrombophlebitis or an active infection;
- On a leg where cuffs would interfere with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg;
- On patients with neuropathy;
- On extremities that are insensitive to pain;
- Where increased venous or lymphatic return is undesirable;

Comparison of Indications

The Indications for Use for the Vena Pro Vascular Therapy System are the same as those for the predicate devices listed on the previous page.

Substantial Equivalence of Technological Characteristics

The Vena Pro Vascular Therapy System is equivalent to the predicate devices listed in function and operating principals to achieve identical results. All predicate systems (*DVTCare CA5-K061125, TriplePlay-K103187, WizAir DVT-K023573, TravelAir-K022340 and Venodyne DVT Advantage-K011318)* utilize microprocessor controlled pumps to deliver approximately 50 mmHg of pressurized air to bladders that are attached to the patient's lower limbs, using a cycle time of approximately 60 seconds / leg. Each cycle consists of inflation of a bladder, followed by a rest period during which the bladder deflates and the limb relaxes without any compression.

Multiple audible and visual safety alarms are built into the system, similar to those built into the *VascuTherm, TriplePlay* and *DVTCare CA5*, including; Low pressure alarms, low battery alarm and system malfunction overpressure safety via an internal safety vent with a release pressure of 2 psi (approximately 100 mmHg).

Cycle and maximum fill times are factory preset and cannot be changed. The default settings are similar to predicate devices in fill time, cycle time and pressure settings. The default pressure setting for the wraps is factory preset at approximately 50 mmHg and cannot be adjusted.

The Vena Pro Vascular Therapy System uses similar means for pressure delivery to the cuffs as the predicate devices. Pressurized air is delivered by the pump to the cuffs via flexible, plastic air tubes connected to the plastic pump / control unit. ***Unlike*** the predicate devices, the connecting tubes between the PVC bladder and the pump unit are very short, and are substantially contained *within the pump housing* and thus not accessible by the user. The pump housing is permanently attached to each single-use wrap and is intended to be disposed of after use.

Like the *DVTCare CA5*, *VascuTherm* and the *TriplePlay,* the Vena Pro cuffs are comprised of single bladder PVC chambers encased in a covering of soft, non-latex, non-woven medical fabric made from Dupont Softesse (a Polyester blend) or equivalent medical material for increased patient comfort and biocompatibility compliance.

As with the *WizAir DVT, TriplePlay* and *TravelAir* systems, the microprocessor and pump units are powered by internal rechargeable batteries, and can be connected to the main AC power line (through the battery charger / AC adaptor) while in use, allowing uninterrupted prolonged service.

Non-Clinical Testing

Non-clinical validation, including electrical safety, EMC, mechanical integrity, environmental and life cycle testing have shown that the Vena Pro Vascular Therapy System has performance characteristics substantially equivalent to or surpassing those of the listed predicate devices. In-house bench testing has verified equivalent pressure delivery, cuff (bladder) fill time, cycle time and overall system performance as the predicate devices listed.

Clinical Testing

No clinical testing was performed on the Vena Pro system, however test results of some predicate devices have been compared in the following published clinical studies:

- Evaluation of Intermittant Pneumatic Compression Devices (Orthopedics 24(3):257-261, 2001);
- Venous hemodynamics after total knee arthroplasty: Evaluation of active dorsal to planar flexion and several mechanical compression devices (Journal of Bone and Joint Surgery, November 1998)

The summary conclusions of both studies state that the use of intermittent pneumatic compression devices is useful in decreasing the risk of postoperative DVT. The Venodyne model used in the studies produced a mean blood flow velocity of 76.2 +/- 23.77 using an average inflation pressure of 43 mmHg, a fill time of 11.6 seconds and a total cycle time of 60 seconds. In that these values are nearly identical to the corresponding default parameters used by the Vena system, and the methods of pressure delivery and operation are identical in both systems, substantial equivalence is concluded.

Summary Conclusion

Per the requirements of 21 CFR 807, surrogate clinical data, non-clinical validation testing and the information provided in the accompanying 510(k) submission, Innovamed Health, LLC concludes that the Vena Pro Vascular Therapy System model VP-3111 is safe, effective and performs in a manner that is substantially equivalent to the predicate devices listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Innovamed Health, LLC
Joe Adkins
2839 Harvest Moon Drive
Orange Park, FL, 32073

Re: K133274
Trade/Device Name: Vena Pro VP-3111
Regulation Number: 21 CFR 870.5800
Regulation Name: Cardiovascular
Regulatory Class: II
Product Code: JOW
Dated: November 14, 2013
Received: November 19, 2013

Dear Mr. Adkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) # K 133274

Indications for Use:

The Vena Pro Vascular Therapy System, model VP-3111, is intended to be an easy to use portable system, prescribed by a physician, for use in the home or clinical setting to help prevent the onset of DVT in patients by stimulating blood flow in the extremities (simulating muscle contractions). This device can be used to:

- Aid in the prevention of DVT;
- Enhance blood circulation;
- Diminish post-operative pain and swelling;
- Reduce wound healing time;
- Aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency and reduction of edema in the lower limbs.

The unit can also be used as an aid in the prophylaxis for DVT by persons expecting to be stationary for long periods of time.

Prescription Use: X	**AND/OR**	**Over-The-Counter Use:**
(Part 21 CFR 801 Subpart D)		**(Part 21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)